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Health Care For All's Public Interest Law Firm

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Dockets Management Branch
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

RE: Docket No. 02N-0209
Comment on Direct to Consumer Advertising of Pharmaceuticals
Public Health Impact

To Whom It May Concern:

Please accept these comments, on behalf of Community Catalyst, Health Care For All and Health Law Advocates, on direct-to-consumer pharmaceutical advertising (DTCA). Community Catalyst is the convener of the Prescription Access Litigation Project (PAL). PAL is a coalition of 84 organizations from 34 states and the District of Columbia whose mission is to reduce the price paid by American consumers for prescription drugs by creating a consumer voice on the key issue of pharmaceutical pricing practices. Health Care For All and its law firm, Health Law Advocates, are Massachusetts-based nonprofit organizations dedicated to making affordable and quality health care available to everyone, regardless of income or social status.

As advocates of improved access to health care, including affordable, therapeutic prescription drugs, we are concerned about the impact of DTCA on consumer behavior, prescribing trends and drug costs. We strongly believe that the FDA's regulation of DTCA[1] is more than justified by the potential public health impact of DTCA, and is consistent with First Amendment free speech law.[2] DTCA was approved in order to expand consumer knowledge of pharmaceuticals, thereby allowing consumers informed participation and choice in their own health care. In order for DTCA to serve this purpose, it is essential that the FDA vigorously

[1] 21 C.F.R. §202.1, as authorized by 21 U.S.C. §352(n), and the Kefauver-Harris Amendment of 1962, PL 87-781, 76 STAT. 780 codified in section 21 U.S.C. §502(n).

[2] The Supreme Court recently held that the FDA's ban on the promotion of compounded drugs by providers violated the First Amendment because it amounted to an undue restriction on free speech. *Thompson v. Western States Medical Center,* 122 S.Ct. 1497 (2002). However, nothing in *Thompson* justifies the elimination of FDA regulation of DTCA. *Thompson* concerns a ban on *all* promotion of compounded drugs, including truthful information. In contrast, the DTCA regulations do not prevent the dissemination of truthful promotional information on approved pharmaceuticals, and only require the inclusion of risk information in the advertisements to help protect consumers. DTCA regulations are minimal and reasonable in comparison to those at issue in *Thompson*.

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impose and maintain standards regarding the type and extent of information that is included in any DTCA. Without these requirements, DTCA will fail to serve the limited and important purpose for which it was first allowed.

I. Introduction

While pharmaceuticals offer the hope of health improvements to many Americans, substantial costs and risks accompany any potential benefits of consuming prescription drugs. Aided in part by direct-to-consumer advertising, our nationwide prescription drug market continues to grow at a phenomenal rate,[3] burdening an increasing number of consumers with the astronomical costs of brand-name drugs as well as the potential health risks posed by consumer-driven prescribing patterns.[4] Although the full extent of DTCA's health effects is a matter of ongoing research,[5] preventive regulation of this powerful industry marketing tool is necessary and prudent to protect the public's health.

These comments support the public health need for the regulation of DTCA, and propose ways in which we believe the FDA's regulations in this area should be strengthened to better protect consumers. First, DTCA influences risk perception, consumer behavior and physician prescribing patterns. Second, adverse drug events (ADEs) due to inappropriate prescribing are a known and dangerous health risk. Third, the pharmaceutical market in the United States has reached unprecedented proportions, and DTCA contributes to rising pharmaceutical consumption. In every sense of the phrase, this is truly a "public health" issue requiring FDA regulation, as vast numbers of Americans shoulder the potential risks, costs, and benefits involved. While the pharmaceutical industry reaps huge profits as a result of its expanded marketing capacity, it should not also enjoy completely unregulated advertising freedom where the public's health may be put at risk. Finally, these comments conclude with recommendations for improved regulation of DTCA.

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[3] Schweitzer, Stuart O. and Comanor, William S. "Chapter Five: Pharmaceutical Prices and Expenditures." Changing the U.S. Health Care System: Key Issues in Health Services Policy and Management. Ed. Ronald M. Andersen, Thomas H. Rice, and Gerald F. Kominski. San Francisco: Jossey-Bass, Inc., 2001.

[4] To Err Is Human: Building a Safer Health System. Ed. Linda T. Kohn, Janet M. Corrigan, and Molla S. Donaldson. Institute of Medicine. Washington: National Academy Press, 2000. p. 33.

[5] Lyles, Alan. "Direct Marketing of Pharmaceuticals to Consumers." Annual Review of Public Health. 23 (2002): 73-91.

II. The Evidentiary Basis for Protecting the Public's Health By Regulating DTCA

1. DTCA Fosters Misperception of Pharmaceutical Risks

Direct-to-consumer advertisements, in both broadcast and print media, manipulate individuals' perceptions of marketed drugs through sleek appeals to emotion. Even while in full compliance with current FDA marketing guidelines, consumer-oriented advertisements "play up the positive features of a drug and down-play the negative or unknown aspects. Side effects... are almost always discussed last [and] are buried in the narrative."[6] This imbalance in risk perception serves the manufacturers' interests, not the consumers'. "When consumers are at least partially aware of health and safety risks, manufacturers have incentives to manipulate risk perceptions in the manner that benefits them most."[7]

Television commercials prove particularly effective in manipulating risk perception. In the dilution of risks by positive aural and visual messages, televised pharmaceutical advertisements "lull" consumers into a state of reduced vigilance regarding self-protection from risk.[8] Evidence shows that viewers of televised prescription drug commercials gain awareness of the benefits of specific drugs and fail to understand all of the potential side effects,[9] resulting in documented "miscomprehension" of drug ads.[10] By using all of the seductive marketing techniques available in this most absorbing, pervasive medium, pharmaceutical manufacturers convince consumers of the benefits of their products while failing to communicate the risks.

Print advertisements also use techniques to downplay risk perception and bolster benefit perception and emotional response. For example, pharmaceutical manufacturers commonly purchase both the front and back of one magazine page for an advertisement. This allows them to display the eye-catching, wholly positive and emotion-oriented message on the front of one page while hiding the "brief summary" of risks and contraindications on the back, often in unreadable and

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[6] Wilkes, Michael S., et al. "Direct-to-Consumer Prescription Drug Advertising: Trends, Impact, and Implications." Health Affairs, 19 (2000): 110-128, 116.

[7] Hanson, Jon D., and Kysar, Douglas A. "Taking Behavioralism Seriously: Some Evidence of Market Manipulation." 112 Harv. Law Review 1420, 1466. (1999).

[8] See footnote 7, p.1456.

[9] "Understanding the Effects of Direct-to-Consumer Prescription Drug Advertising." The Henry J. Kaiser Family Foundation. (Nov. 2001).

[10] See footnote 9, generally.

unappealing type. Deciphering the "brief summary" requires a professional-level reading proficiency and a grasp of biostatistics, such that these advertisements fail to communicate risk or efficacy information to most consumers. Considering that the vulnerable elderly, in particular, make up a large percentage of prescription drug consumers, the opaqueness of this risk information may prevent any meaningful communication. Pharmaceutical companies use both broadcast and print media to present stylish advertisements that appeal to deep fear, anxiety, and hope, while obscuring or down-playing risk information, in order to influence patient's perceptions of how the advertised drugs may improve their lives.

Our national experience with product advertisement and public health, particularly the lessons learned from the tobacco industry's mass marketing campaigns, provides a cautionary tale against allowing the manufacturers of potentially harmful products to enjoy unregulated marketing freedom. While we do not equate potentially beneficial pharmaceutical advertising to the intentionally misleading tobacco campaigns, comparing the two industries illustrates how manufacturers influence consumer behavior with well-crafted product promotion. For example, through the presentation of glossy, seductive advertisements meant to target very specific public concerns, tobacco manufacturers succeeded in lowering consumer risk perceptions.[11] The tobacco industry effectively responded to trends in consumer culture, for example, by promoting "low-tar" cigarettes as a "healthier" alternative when public awareness of smoking risks began to increase.[12] Even more troubling, tobacco advertisements "succeeded in creating demand...by conveying to smokers a sense of independence, autonomy, and sexuality."[13] Instead of focusing on the cigarette products themselves, many advertisements promoted wonderful feelings associated with consuming the products.[14]

Similarly, pharmaceutical advertisements promote prescription drugs through highly stylized campaigns that appeal to emotion. Consider the Viagra advertisement showcasing an attractive middle-aged man zooming around a race track behind the wheel of a sports car, or the advertisement for Rogaine hair loss treatment, where a good-looking female "state[s] unequivocally, 'I know that a man who can afford Rogaine is a man who can afford me.'"[15] These ads, echoing the

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[11] See footnote 7, p. 1469.

[12] See footnote 7, p. 1473

[13] See footnote 7, p. 1471

[14] See footnote 7, p. 1471.

[15] See footnote 7, p. 1471.

manipulative techniques used in the tobacco product campaigns, also influence consumer perceptions and behavior by insidiously playing to emotion.

2. DTCA Influences Physician Prescribing Patterns

Advertising-induced patient demand may adversely influence physicians' prescribing patterns. In fact, physicians cite patient demand as the most common reason for inappropriate prescribing.[16] The influence of DTCA may substantially increase the potential for ill-considered, patient-driven prescribing decisions, particularly within managed care systems where physicians face limitations on the amount of time they can spend with each patient. Furthermore, in a health care culture increasingly dominated by notions of patient autonomy and collaborative patient-physician relationship models, patient demand plays a crucial role in determining the course of treatment. Although objective information about therapeutic options and possible side effects may empower patients and lead to informed conversations with providers, direct-to-consumer advertising does not necessarily effect such a balanced approach.

3. Adverse Drug Events Pose Serious Risk to Consumers

Nationwide growth in pharmaceutical consumption threatens "sizable and increasing numbers of people" with adverse drug events from medication errors.[17] One compelling analysis of "62,216 visits to an emergency department... found that 1,074 (1.7 percent) were related to medication noncompliance or inappropriate prescribing."[18] Evidence also shows that the number of medication-related deaths between 1983 and 1993 increased at a faster rate for outpatients (8.48-fold) than for inpatients (2.57-fold), reflecting our new national appetite for pharmaceuticals.[19] Furthermore, outpatient adverse drug events are estimated to account for between 2.4 and 11 percent of hospital admissions, a majority of which are preventable, as well as an increasing number of visits to physician offices and emergency departments.[20] Prescription drugs, while offering therapeutic benefit, also cause serious harm. In light of this potentially serious harm, it is critical that DTCA be as accurate and informative as possible.

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[16] Schwartz, RK, Soumerai, SB, and Avorn, J. "Physician Motivations for Nonscientific Drug Prescribing." Social Science and Medicine 28 (1989): 577-582.

[17] See footnote 4.

[18] See footnote 17, p. 35

[19] See footnote 17, p. 32-33

[20] See footnote 17, p. 35

4. The Pharmaceutical Market in the United States Affects a Sizeable and Growing Number of Consumers

The current prescription drug market in the United States surpasses all previous proportions.[21] As a country, we consume more[22] and pay more for[23] our pharmaceuticals than ever. For example, between 1993 and 1998, the number of prescriptions filled increased from 1.9 to 2.5 billion.[24] Within the same interval, "the number of antidepressant prescriptions filled increased by 111 percent, and that for cholesterol-lowering drugs rose by 162 percent. For oral antihistamines, the increase was fully 500 percent."[25] Furthermore, the categories with the greatest increases are also those most commonly advertised. The bill for this increased consumption hits consumers hard. Patient spending on prescription drugs jumped more than 17 percent in 2001, to $175.2 billion.[26]

The increasing demand and rising profits in the pharmaceutical industry result in part from aggressive direct-to-consumer advertising.[27] Between 1996 and 2000 alone, the industry increased spending on DTCA by 212 percent, and by a factor of 7 for televised DTCA in particular.[28] Manufacturers target the consumer through broadcast media with good reason. The pervasiveness of television exposure in the average American home provides a powerful marketing opportunity. By some measures, the average American household watches over

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[21] See footnote 3.

[22] See footnote 3.

[23] Freudenheim, Milt. "Drug Spending Rises Sharply at Pharmacies and by Mail." New York Times 29 Apr. 2002, Washington ed.:. A18.

[24] See footnote 23.

[25] See footnote 3.

[26] See footnote 23. The $175.2 billion total includes $154.5 billion spent on prescriptions filled in pharmacies as well as $20.7 billion spent on mail-order prescription filling services.

[27] See footnote 23. See also: Waxman, Judith, Deputy Executive Director of Families, USA. Testimony before the U.S. House of Representitives Committee on Government Reform Subcommittee on National Security, Veterans Affairs and International Relations. Boston, Mass., 22 July 2002., and Rosenthal, Meredith B., et al. "Promotion of Prescription Drugs to Consumers." The New England Journal of Medicine. 346 (2002): 498-505.

[28] See footnote 6, p. 116.

four hours of television per day.[29] Approximately 76 percent of American homes have 2 or more televisions, and the television is on for 7 hours, 40 minutes per day on average in each home.[30]

In the face of this powerful marketing opportunity, and with some state governments pushing legislation to curb direct-to-*provider* marketing techniques,[31] DTCA is likely to become an even more prominent method of pharmaceutical promotion in the near future. Although drug manufacturers still spend most of their advertising dollars promoting drugs to providers,[32] DTCA continues to grow disproportionately,[33] evincing the growing interest of manufacturers in promoting drugs directly to patients. Furthermore, evidence demonstrates that DTCA is just as effective, if not more, than direct-to-provider advertising.[34] The possibility of shifting an increasing proportion of promotional dollars to DTCA, while experiencing the same huge profits, would allow the pharmaceutical industry to market in a realm that may be less vulnerable to legislative reform.[35]

One would hope that the growing magnitude of the pharmaceutical market only bodes well for the health of the public. However, to assume as much and allow the proliferation of unregulated DTCA would put Americans at risk. Given the prevalence and severity of adverse drug events from inappropriate prescribing, the behavioral effects of DTCA, and the ability of consumers to influence physician prescribing patterns, there is considerable public health justification for continuing

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[29] "Facts and Figures about our TV Habit." TV Turnoff Network, at http://www.tvfa.org/images/facts&figs/factsheets/Facts%20and%20Figures.pdf, accessed 4.28.02. Citing: Neilsen Media Research 2000.

[30] See footnote 29.

[31] For example, on June 13, Vermont Gov. Howard Dean signed a bill to "require pharmaceutical company representatives to publicly disclose all gifts valued at or above $25, excluding drug samples, given to doctors, hospitals, and nursing homes." Proponents hope the bill will discourage providers from prescribing more expensive brand-name drugs due to the influence of physician-oriented advertisements. "Vermont Governor Signs Bill Requiring Reporting of Gifts to Doctors by Drug Companies." Kaisernetwork.org Daily Health Policy Report, Prescription Drugs, 14 June 2002. Retrieved from: http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=3&DR_ID=11739.

[32] Rosenthal, Meredith B., et al. "Promotion of Prescription Drugs to Consumers." The New England Journal of Medicine. 346 (2002): 498-505.

[33] See footnote 32.

[34] See footnote 32.

[35] See footnote 31.

to require the balanced presentation of risk information in pharmaceutical advertisements. The FDA must continue to uphold its mandate to protect the public's health[36] by regulating the content of DTCA.

III. Recommendations for Strengthening the FDA's Regulation of DTCA to Protect the Public Health

Many aspects of the FDA's current regulation of DTCA[37] serve the interests of public health, particularly the required inclusion of risk information in advertisements that explicitly promote drug benefits. It is imperative, in light of the public health risks involved in advertising potentially dangerous pharmaceutical products, to maintain at least this baseline level of consumer protection. Three key areas in the FDA regulations require adjustments that would serve the public health but not unduly infringe on the pharmaceutical industry's right to advertise freely.

1. FDA Regulations Should Require Clear, Balanced Risk Information In All DTCA

Consumers deserve clear, complete risk information in all pharmaceutical advertisements. Currently, drug commercials put the onus on the consumer to seek out a balanced understanding of a drug's risks and benefits, which does nothing to protect the public from the important (and usually only) impression of a drug made by its advertisement. Our suggested modifications to the FDA regulations would prevent DTCA from communicating imbalanced risk/benefit messages. First, for broadcast advertisements, because most individuals watch television or listen to the radio in a relatively passive state, the FDA should temper the distracting positive auditory and visual messages that embroider risk messages in DTCA. For example, the FDA should require manufacturers to ***present risk information in louder, clearer, more audible voice-overs.*** For print advertisements, manufacturers should have to ***print risk information in highlighted text boxes on the main promotional advertisement,*** not relegated to the unreadable "brief summary" on the opposite side of the page.

In addition, we urge the FDA to require ***the inclusion of understandable efficacy information*** in DTCA. This information is meaningful and important in

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[36] The 1938 Food, Drug and Cosmetic Act gave the U.S. Food and Drug Administration its mission, which includes promotion of the public health through "appropriate action on the marketing of regulated products," and protection of the public health in "ensuring that...human and veterinary drugs are safe and effective." 21 U.S.C. §393 (b).

[37] See footnote 1.

making treatment decisions, and if DTCA is serving the educational purpose for which it was initially approved, presentation of efficacy information is indispensable. The efficacy data in most "brief summaries" are far too technical to communicate anything meaningful to consumers. Instead, we recommend that the FDA require manufacturers to distill results from drug trials in a one- to two-line, easily understood efficacy statement, which must be included in all DTCA "major risk statements." This would help ensure that DTCA serves an educational, awareness-raising purpose, as originally intended, instead of allowing it to mislead consumers for the financial benefit of pharmaceutical manufacturers.

2. FDA Regulations Should Eliminate the "Reminder Advertisement" Exception to Required Inclusion of Risk Information

One way to combat inappropriate prescribing would be to limit the ability of manufacturers to cultivate brand-name popularity through "reminder advertisements" without disclosing product risks. For this type of DTCA, the FDA currently waives its risk disclosure requirements if the manufacturer refrains from describing the drug's benefits or indications.[38] This ***waiver of risk inclusion requirements should be eliminated.*** Allowing prescription drug suppliers to induce consumer demand and reinforce irrational preferences for certain brands may have negative public health implications, including both rising drug expenditures and increased incidence of adverse drug events.

Furthermore, "reminder advertisements" fail to serve any identifiable educational purpose. They allow the manufacturer of a drug to enjoy an exemption from describing its risks, while still using the mass media to imply benefits and reinforce a glamorous brand-name image for the product. "Reminder advertisements" foster "'irrational' consumer preferences"[39] in the hopes of developing patient brand loyalty. This marketing technique may help account for the fact that in 2001 the 50 drugs with the largest price increases were brand-name options, and they showed disproportionately high increases in sales: 34 percent compared to an average of 9 percent.[40]

3. The FDA Should Continue to Prohibit Advertisement of Off-Label Uses

Allowing the advertisement of off-label drug uses would subvert the FDA drug approval process and put the public health at risk. Permitting off-label DTCA would reinforce an incentive for manufacturers to submit drugs to the FDA

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[38] 21 CFR 202.1(e)(2)(i)

[39] McCarthy, S. "McCarthy on Trademarks and Unfair Competition." S 2:38, 4th ed.

[40] See footnote 23.

only for those indications that are easiest to approve for sale (where, for example, efficacy is easy to prove), and then promote more lucrative, unapproved uses to physicians and consumers. Because physicians may legally prescribe drugs for unapproved uses, off-label drug sales are only limited by the manufacturer's capacity to convince physicians and consumers of the off-label benefits. Off-label DTCA would drastically expand this marketing capacity and effectively replace the FDA's drug approval process with promotional campaigns. The FDA would be sanctioning the use of unapproved drugs and putting consumers at risk. We are opposed to allowing DTCA of off-label prescription drug products because of the considerable risks to consumers.

IV. Conclusion

The FDA must continue to regulate the advertisement of pharmaceuticals to protect the public from the dangers of consumer-driven prescribing patterns and adverse drug events. ***DTCA regulations should require all advertisements to include some mention of risks and efficacy data, and this information should be presented in a clear, easy-to-understand format.*** These small measures may help offset the documented confusion and misperceptions that result from the bombardment of positive messages inherent in current DTCA. While FDA's regulations should respect the pharmaceutical industry's right to advertise its products, the burdens of effective risk communication in DTCA are minimal, and pale in comparison to the potential public health burden imposed by unregulated DTCA.

Thank you for your consideration. If you have any questions please contact Clare McGorrian at Health Law Advocates.

Sincerely,

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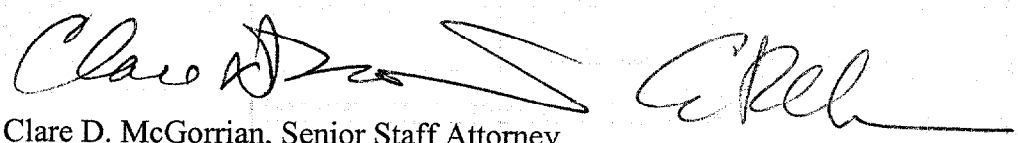
Prescription Access Litigation Project Director
Community Catalyst

Michael Miller, Policy Director
Health Care For All



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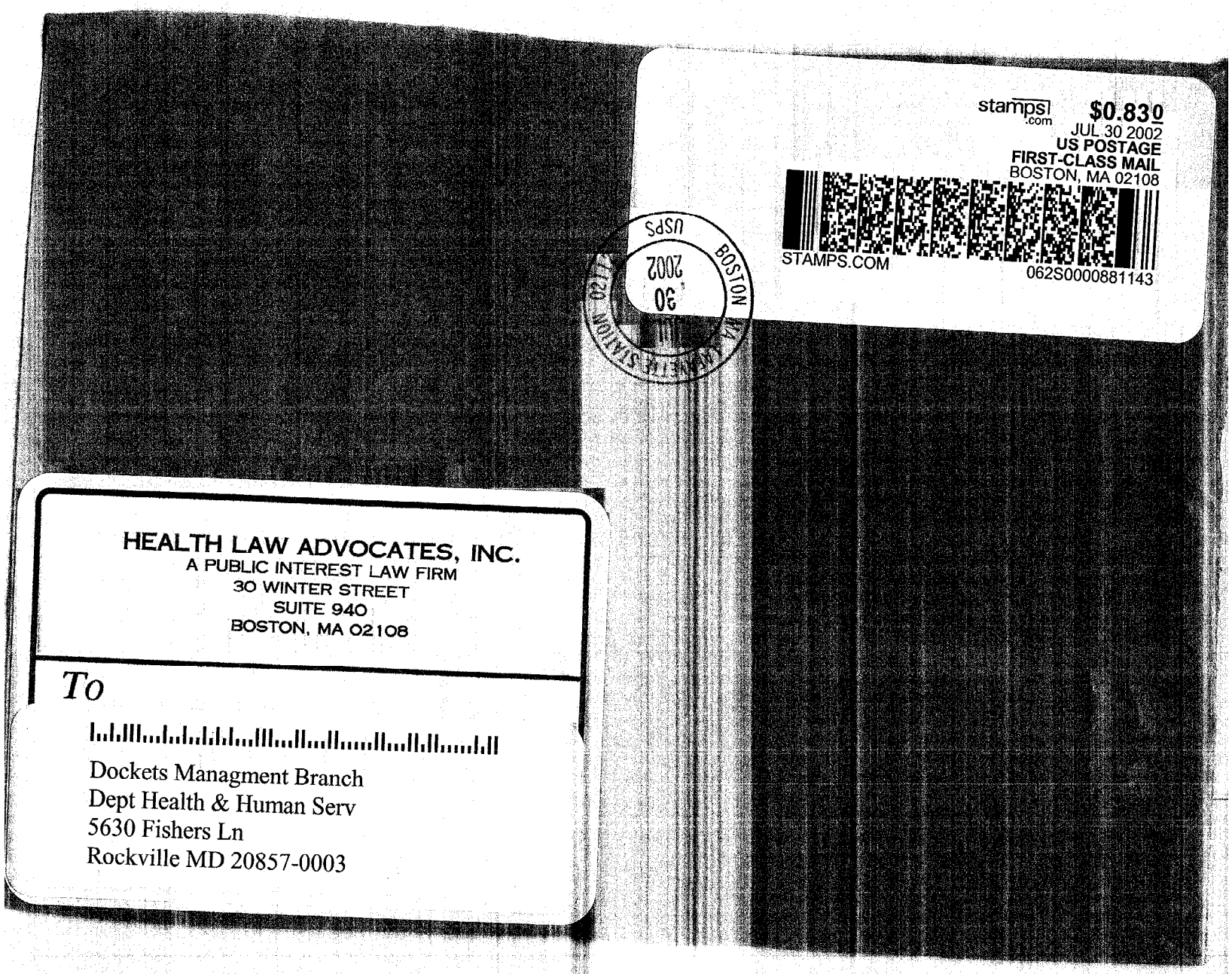
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